REMARKS

Claims 1-27 are currently pending in the present application. In the Office Action mailed July 28, 2003, claims 1-6, 9-12, 18, 23, 26, and 27 stand rejected under 35 U.S.C. §102(b). In addition, claims 1, 7, 8, and 12-25 stand rejected under 35 U.S.C. §103(a).

Claims 1-6, 11, 12, 18, 23, 26, and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Pat. No. 6,067,988, issued to Mueller et al. (Mueller). For a reference to anticipate a claim under 35 USC §102 the reference must teach every element of the claimed invention. (see MPEP §2131).

Mueller is directed to a method for the creation of drug delivery and/or stimulation pockets in myocardium. The method taught by Mueller includes providing a mechanical excising apparatus having proximal and distal ends and a tissue trapping mechanism, the distal end having a tapered dilator tip, the proximal end having a controller operably connected to the tissue and trapping mechanism, placing by surgical incision the distal end of the excising apparatus at a surface of target tissue to be revascularized, advancing the distal end of the excising apparatus within the target tissue by causing the dilator tip to tunnel into the target tissue, operating the controller to open the tissue entrapping mechanism enabling a portion of the target tissue to bulge into the open tissue and trapping mechanism. The tissue entrapping mechanism is permitted to close and cut the bulged portion from the target tissue, the cut tissue being trapped within the excising apparatus. Thereafter, the excising device is withdrawn from the patient.

Claim 1 of the present application is directed to a medicament delivery system and includes an energy source for providing energy to remove or displace tissue, a medicament source comprising a medicament deliverable to tissue, an energy transmitting member having an inlet and for coupling to the energy source and an outlet and disposed at the distal portion for emitting energy, a medicament delivery member comprising an inlet and for coupling to the medicament source and at least one lumen through the medicament delivery member for delivering a medicament, and an outlet and disposed at the distal portion terminating in a tissue engaging surface and having at least one deployable tissue stabilizing member position thereon. The at least one deployable tissue stabilizing member is in communication with at least one lumen positioned within the medicament delivery member. Mueller fails to disclose a medicament delivery member having an outlet and disposed at the distal portion terminating in a tissue engaging surface and having at least one deployable tissue

stabilizing member positioned thereon. Rather, Mueller discloses a device having a tapered dilator tip which is insertable into tissue and useful in excising a portion thereof. As such, Mueller fails to teach or suggest all the claim limitations of the medicament delivery system of the present application. The Applicant respectfully submits that claim 1 is patentable over the cited reference. For at least the same reasons, the Applicant respectfully submits that claims 2-6 and 11, which depend on claim 1, are also patentable.

Claim 12 of the present application is directed to a medicament delivery system and includes an energy source for providing energy to remove or displace tissue, a medicament source for providing a medicament to tissue, an energy transmitting member having an inlet and for coupling to the energy source and an outlet and disposed at the distal portion for emitting energy, a medicament delivery member having an inlet and for coupling to the medicament source and at least one lumen through the medicament delivery member for delivering medicament, a distal portion terminating in a tissue engaging surface having at least one sealing member positioned thereon, the at least one sealing member in communication with at least one lumen positioned within the medicament delivery member, and an operator interface which receives the energy transmitting member and the medicament delivery member. Mueller fails to disclose a distal portion terminating in a tissue engaging surface having at least one sealing member positioned thereon. Therefore, Mueller fails to teach or suggest all the claim limitations of claim 12. As such, the Applicant respectfully submits that claim 12 is patentable over the cited prior art reference.

Claim 18 of the present application is directed to a method for delivering a medicament to tissue and includes providing access to the tissue, deploying a tissue stabilizer, stabilizing the tissue, forming a pocket within the stabilized tissue by removing or displacing tissue, and providing a medicament directly to the stabilized tissue surrounding the pocket. In contrast, Mueller discloses advancing the distal end of the excising apparatus within the target tissue by causing the dilator tip to tunnel into the tissue and operating the controller to open the tissue entrapping mechanism to cut a portion of the target tissue therefrom. As such, Mueller fails to teach or suggest stabilizing tissue prior to the formation of the pocket and prior to the insertion of medicament into the pocket. Therefore, Mueller fails to teach or suggest all the claim limitations as disclosed in claim 18 of the present application. The Applicant respectfully submits that claim 18 is patentable over the Mueller reference.

Claim 23 of the present application is directed to a method for delivering medicament to tissue and includes providing access to the tissue, actuating at least one sealing member to isolate the tissue, forming a channel in the isolated tissue by removing or displacing tissue, and providing medicament directly to the isolated tissue surrounding the channel. Mueller fails to disclose actuating at least one sealing member to isolate the tissue and providing medicament directly to the isolated tissue surrounding the channel. Therefore, the Applicant respectfully submits Mueller fails to teach or suggest all the claim limitations of claim 23. As such, the Applicant respectfully submits claim 23 is patentable over the cited prior art.

Claim 26 of the present application is directed to a method of delivering medicament to tissue and includes providing access to the tissue, biasing a flexible ablation and injection device with a biasing member, forming a channel in the tissue by removing or displacing tissue, and providing medicament directly to the isolated tissue surrounding the channel. Mueller fails to teach or suggest a flexible ablation and injection device. Rather, Mueller includes a central rigid hollow cylinder 46 running the length of a longitudinal axis of the excising assembly 17. (See column 7, lines 54-56). As such, the Applicant respectfully submits that Mueller fails to teach or suggest all the claim limitations of claim 26 of the present application. Therefore, the Applicant respectfully submits that claim 26 is patentable over the cited prior art reference. For at least the same reasons, the Applicant respectfully submits that claim 27, which depends on claim 26, is also patentable.

Claims 1-6, 9-12, 18, 23, 26, and 27 of the present application stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,925,012, issued to Murphy-Chutorian et al. (Murphy-Churtorian). Murphy-Churtorian is directed to devices for laser assisted drug delivery and includes at least one drug inlet for receiving and transmitting through one or more drugs, at least one laser inlet for receiving and guiding a laser delivery device, and a common tube in communication with the at least one drug inlet and the at least one laser inlet such that a distal end of the laser delivery device is extendable through the at least one laser inlet and the common tube to the one or more target areas for the treatment thereof. The one or more drugs may include one or more liquid, semi-solid or solid formations dispensed into the drug inlet and through the common tube.

As stated above, claim 1 of the present application discloses a medicament delivery system having an outlet end disposed at the distal portion terminating in a

tissue engaging surface and having at least one deployable tissue stabilizing member positioned thereon. The at least one deployable tissue stabilizing member is in communication with at least one lumen positioned within the medicament delivery member. Murphy-Churtorian fails to include at least one deployable tissue stabilizing member in communication with at least one lumen positioned within the medicament delivery member. As such, the Applicant respectfully submits that Murphy-Churtorian fails to teach or suggest all the claim limitations of the medicament delivery device of the present application. For at least the same reasons, the Applicant respectfully submits that claims 2-6 and 9-11, which depend on claim 1, are also patentable.

Claim 12 of the present application is directed to a medicament delivery system having a distal portion terminating and a tissue engaging surface having at least one sealing member positioned thereon. The at least one sealing member is in communication with at least one lumen positioned within the medicament delivery member. The Applicant respectfully submits that Murphy-Churtorian fails to include at least one sealing member positioned on the medicament delivery system in communication with at least one lumen positioned therein. As such, the Applicant respectfully submits that claim 12 is patentable over the cited prior art.

Claim 18 of the present application is directed to a method for delivering medicament to tissue and includes deploying a tissue stabilizer, stabilizing the tissue, and forming a pocket in the stabilized tissue by removing or displacing tissue. Murphy-Churtorian fails to disclose deploying the tissue stabilizer and stabilizing the tissue and forming a pocket in the stabilized tissue by removing or displacing tissue. As such, the Applicant respectfully submits that Murphy-Churtorian fails to teach or suggest all the claim limitations of claim 18 of the present application.

Claim 23 of the present application is directed to a method for delivering medicament to tissue and includes providing access to the tissue, actuating at least one sealing member to isolate the tissue, forming a channel in the isolated tissue by removing or displacing tissue, and providing medicament directly to the isolated tissue surrounding the channel. Murphy-Churtorian fails to disclose actuating at least one sealing member to isolate the tissue and providing medicament directly to the isolated tissue surrounding the channel. Therefore, the Applicant respectfully submits that Murphy-Churtorian fails to teach or suggest all the claim limitations of claim 23. As such, the Applicant respectfully submits claim 23 is patentable over the cited prior art.

Claim 26 of the present application is directed to a method for delivering a medicament to tissue and includes providing access to the tissue, biasing a flexible ablation and injection device with a biasing member, forming a channel in a tissue by removing or displacing tissue, and providing a medicament directly to the isolated tissue surrounding the channel. Murphy-Churtorian fails to disclose biasing a flexible ablation and injection device with a biasing member as recited in claim 26 of the present application. As such, the Applicant respectfully submits that Murphy-Churtorian fails to teach or suggest all the claim limitations of claim 26 of the present application. For at least the same reasons, the Applicant respectfully submits that claim 27, which depends on claim 26, is also patentable.

Claims 1, 7, 8, and 12-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mueller in combination with United States Patent Application Publication No. US 2001/0049497, naming Kalloo et al. as inventors. (Kalloo). To establish a prima facie case of obviousness, three basic criteria must be met by the Examiner. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (see MPEP §2143.03).

As described above, Mueller is directed to methods for the creation of drug delivery and/or stimulation pockets in myocardium. The tapered dilator tip of the Mueller device is advanced into the tissue and used to excise a portion of the tissue therefrom. (See column 8, lines 42-49). Kalloo is directed to methods and devices for diagnostic and therapeutic interventions in the peritoneal cavity and discloses an elongated hollow flexible tube having an interior passage sized to receive and allow a passage of an endoscope, the tube having an open distal end, first and second inflatable balloon structures defined adjacent to the distal end of the tube, and an inflation conduit extending respectively from the first and second balloon structures to receive inflation ports disposed adjacent to a proximal end of the tube for this selective independent inflation and deflation of the balloon structures.

As stated above, the medicament delivery system recited in claim 1 of the present application includes an outlet end disposed at the distal portion of the medicament delivery member terminating in a tissue engaging surface and having at least one deployable tissue stabilizing member positioned thereon. The at least one

deployable tissue stabilizing member is in communication with at least one lumen positioned within a medicament delivery member. Neither Mueller nor Kalloo disclose the distal portion of a medicament delivery member having a tissue engaging surface and at least one deployable tissue stabilizing member positioned thereon and in communication with at least one lumen positioned within the medicament delivery member. Mueller fails to disclose at least one deployable tissue stabilizing member positioned on the medicament delivery member, while Kalloo discloses a flexible endoscope having a sterile over tube with anchoring balloons positioned thereon. As such, Kalloo fails to disclose a medicament delivery system having an energy source, a medicament source, an energy transmitting member, and a medicament delivery member. In combination, Mueller and Kalloo, either individually or in combination, fail to teach or suggest all the claim limitations of claim 1. As such, the Applicant respectfully submits that claim 1, and claims 7 and 8 which variously depend on claim 1, are patentable over the cited prior art references.

Claim 12 of the present application is directed to a medicament delivery system and includes an energy source for providing energy to remove or displace tissue, a medicament source for providing a medicament to tissue, an energy transmitting member having an inlet end for coupling to the energy source and an outlet and disposed at the distal portion for emitting energy, a medicament delivery member having an inlet end for coupling to the medicament source and at least one lumen through the medicament delivery member for delivering medicament, and a distal portion terminating in a tissue engaging surface having at least one sealing member positioned thereon and in communication with at least one lumen positioned within the medicament delivery member, and an operator interface which receives the energy transmitting member and the medicament delivery member. As stated above, Mueller fails to disclose a distal portion terminating in a tissue engaging surface having at least one sealing member positioned thereon and in communication with at least one lumen positioned within the medicament delivery member, while Kalloo fails to disclose a medicament delivery system having an energy source for providing energy, a medicament source for providing medicament, an energy transmitting member, or a medicament delivery member. Therefore, in combination Mueller and Kalloo, either individually or in combination, fail to disclose a distal portion of a device terminating in a tissue engaging surface having at least one sealing member positioned thereon and in communication with at least one lumen positioned within a medicament delivery member. As Mueller and Kalloo fail to teach or suggest all the claim limitations of independent claim 12, and dependent claims 13-15 which depend from claim 12, the

Applicant respectfully submits that claims 12-15 are patentable over the cited prior art references.

Claim 16 of the present application is directed to a medicament delivery system and includes an energy source for providing energy to remove or displace tissue, a medicament source for providing medicament to tissue, an energy transmitting member having an inlet and for coupling to the energy source in a flexible outlet and disposed at the distal portion for emitting energy, a medicament delivery member having an inlet and for coupling to the medicament source and at least one lumen through the medicament delivery member for delivering medicament, a flexible distal portion terminating in a tissue engaging surface having at least one deployable biasing member positioned thereon and in communication with at least one lumen positioned within a medicament delivery member, and an operator interface which receives the energy transmitting number and medicament delivery member. As stated above, the Mueller device includes a common central rigid hollow cylinder running the full length of the longitudinal axis of the excising assembly. (See column 7, lines 52-56). The Kalloo device fails to disclose a flexible distal portion terminating in a tissue engaging surface having at least one deployable biasing member positioned thereon. The Applicants respectfully submit that the combination of Mueller and Kalloo is inoperable. Mueller discloses a device having a common central rigid hollow cylinder running the full length of the longitudinal axis of the excising assembly. Kalloo discloses a flexible sheath through which an endoscope may be inserted. Therefore, Mueller and Kalloo teach away from each other. Moreover, a combination of Mueller and Kalloo provides a rigid device insertable through a flexible sheath. As such, the Applicant respectfully submits Mueller and Kalloo, either alone or in combination, fail to teach or suggest all the claim limitations recited in claim 16 and 17 of the present application. As such, the Applicant respectfully submits that claim 16 and 17 are patentable over the cited prior art references.

With respect to the rejections to claims 1, 7, 8, and 12-17, the Applicant respectfully submits that the Examiner has failed to show motivation to combine Mueller and Kalloo. Rather, the Applicant submits that the Examiner has attempted to reconstruct the present invention utilizing hindsight, which is inappropriate. See, In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir.1999).

Claim 18 of the present application is directed to a method for providing a medicament to tissue and includes providing an access to the tissue, deploying a tissue

stabilizer, stabilizing the tissue, forming a pocket in a stabilized tissue by removing or displacing tissue, and providing medicament directly to the tissue surrounding the pocket. Mueller fails to disclose or suggest deploying a tissue stabilizer in stabilizing the tissue, while Kalloo fails to disclose forming a pocket in a stabilized tissue by removing or displacing tissue. As such, the Applicant respectfully submits that Mueller and Kalloo, either alone or in combination, fail to teach or suggest all the claim limitations of claim 18. Moreover, the Applicant respectfully submits that the Examiner has failed to show a motivation to combine the Mueller and Kalloo references, and again has used impermissible hindsight to recreate the Applicant's device. The Office Action mailed July 28, 2003, states "the teachings of Mueller and Kalloo et al. and the motivations for combinations are essentially those already set forth regarding claims 1, 7, 8, and 12-17 above. Thus it would have been obvious to the artist in of ordinary skill to combine these old and well-known teachings and to employ a plurality of barbs, since this is merely the provision of multiple structures for multiplied effect and is notorious in the art, thus producing a method such as claimed." The Applicant respectfully submits that the Examiner's factual assertion that the deployment of a plurality of barbs on a medicament delivery device is well-known in the art is not properly officially noticed and not properly based upon common knowledge.

Claim 23 of the present application is directed to a method for delivering a medicament tissue and includes providing access to tissue, actuating at least one sealing member to isolate the tissue, forming a channel in the isolated tissue by removing or displacing tissue, and providing a medicament directly to the isolated tissue surrounding the channel. Mueller fails to disclose or suggest actuating at least one sealing member to isolate the tissue and forming a channel in the isolated tissue by removing or displacing tissue, while Kalloo fails to disclose forming a channel in an isolated tissue by removing or displacing tissue and providing a medicament directly to the isolated tissue surrounding the channel. Therefore, the Applicant respectfully submits that Mueller and Kalloo, either individually or in combination, fail to teach or suggest all the claim limitations of claim 23. Therefore, at claims 23 and 24 are patentable to the cited prior art references.

In view of the foregoing, it is submitted that all pending claims are in condition for immediate allowance, and such action is respectfully requested. However, if for any reason direct communication with the Applicant's attorney would serve to advance prosecution of this case to finale, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number. The commissioner is authorized to

charge any fee which may be required in connection with this amendment to the two deposit account number 50-1329.

In view of the foregoing, it is submitted that all pending claims are in condition for immediate allowance, and such action is respectfully requested. However, if for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this matter to deposit account No. 50-1329.

Respectfully submitted,

Dated: Nov 21, 2003

Brian F. Swienton
Registration No. 49,030

STRADLING YOCCA CARLSON & RAUTH
660 Newport Center Drive, Suite 1600
Newport Beach, CA 92660
Telephone: (949) 725-4198
Facsimile: (949) 823-5198

Customer Number: 31,278